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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/720,513 | 03/26/2001 | Therese Jourdiar | MBHB00-1282 | 3546 |
| 20306 | 7590 | 12/13/2005 | EXAMINER | |
| MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606 | | | LI, BAO Q | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,513

Applicant(s)

JOURDIER ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/22/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Declaration filed on Sept. 22, 2005 has been acknowledged.

Claims 10-15 are pending.

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/22/2005 has been entered. The RCE follows:

Claim Rejections - 35 USC § 103

Claims 10-15 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Carrano et al. (WO 95/26718A1), Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403), Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut) and Bouvet et al. (Infect. Immun. 1994, Vol. 62, pp. 3957-3961) under the same ground as stated in the previous Office Action, which is substantiated by Anderson et al. (J. Infect. Dis. 1989, Vol. 160, No. 6, pp. 960-969) and Nell Tharpe (Google Books.).

In response to the previous Office Action, applicants filed a Declaration under 37 CFR 1.132. By this Declaration, Dr. Theresa-Marrie Jourdir concluded that there is no specific anti-gp160 IgA were present in the vaginal or rectal secretions when the antigen is administered dejectedly at the targeted site and that administration to the thigh gives a substantially and significantly greater specific antig-gp160 response in the rectogenitourinary region compared to adminsteration to the deltoid since the data demonstrated that for the claimed invention the immune response is lesser closer to the site of administration.

The declaration and argument have been respectfully considered; however, they are not persuasive to making above conclusions and overcome the rejection. Because based on the data presented in the Declaration filed on 09/22/2005, one can only make the conclusion that thigh injection can induce significant specific immune response than the injection via remote muscle, i.e. deltoid. However, one cannot make a conclusion that the injection of an HIV antigen on thigh

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muscle can induce more significant specific immune response to said antigen than the injection via another closer area, e.g. VR since there is no any group presented in this declaration teaches to inject same amount gp160 antigen into VR with the same condition to the injection of said antigen into thigh.

While in the last Declaration filed on Feb. 22, 2005, the Declaration does not contain a group I of injecting HIV gp169 MN/LAI into VR, there is not group comprising to use gp160 injected to the thigh compared with group I. All the thigh injection groups comprise more than one times of antigen injection. Therefore, one cannot make the conclusion that increase the immune response by thigh injection is more significant than the injection via VR.

Moreover, Applicants' argument alone with the declaration cannot answer the questions raised in the previous Office Action, i.e. why thigh injection as a known and very common immunization site is a non-obvious selection and only the antigen selected from the sex transmitted disease has such unobvious local immune response pattern than any other pathogenic antigen. Otherwise, applicants cannot overcome the obvious rejection by conclusion that the claimed method is an unexpected result.

Nevertheless, the thigh injection is a common place for immunizing sex transmitted disease, such as HIV, which is substantiated by Aderson et al. (lines 6-9 on 1st column of page 962) and HSV, which is substantiated by Nell Tharpe in Clinical Practice Guidelines for Midwifery & Woman's Health, in which he discloses that recombinax HB mcg/0.5 ml U is muscular injected into the anterior thigh at the birth... when primary infection with HBV occurs during pregnancy (See attached citation: Clinical practice guide for midwife from the Google Books). More importantly, Stities et al. and Groswasser et al. cited in the previous office action teach that thigh injection is preferred immunization sites for inducing a local immune response stated in the previous office action.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

1. This is a same application of applicant's earlier Application No. 09,720,513. All claims are drawn to the same invention claimed in the earlier application and could have been finally

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rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

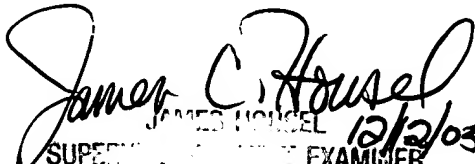
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

12/06/2006


JAMES HOUSEL
SUPERVISOR
TECHNICAL CENTER 1600
12/12/05